

510(k) Summary

K130181

JUL 31 2013

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 07/18/2013

1. Applicant / Submitter:

Infopia Co., Ltd.
891, Hogle-Dong, Dongan-Gu, Anyang, Kyunggi, Republic of Korea 431-080

Contact: Sunmi Shin
Phone +82 31 460 0300
Fax +82 31 460 0401

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
1515 E Katella Ave Unit 2115,
Anaheim, CA 92805,
Phone: 714-202-5789 Fax: 714-409-3357
Email: info@lkconsultinggroup.com

3. Device:

- Device's Trade Name: GluNEO™ Glucose Monitoring System
GluNEO™ Professional Glucose Monitoring System
- Device's Common Name: Blood Glucose Test System
Quality control material (assayed and unassayed)
- Device's Classification Name: Glucose Dehydrogenase
Single (specified) analyte controls
Calculator/data processing module for clinical use
- Classification Regulation: 21CFR 862.1345
21CFR 862.1660
21CFR 862.2100
- Classification Product Code: LFR, NBW, JJX, JQP

4. Predicate Device:

Ascensia® CONTOUR® Blood Glucose Monitoring System (K062058) by Bayer HealthCare, LLC.

5. Description:

The GluNEO™ Blood Glucose Monitoring System consists of a meter, test strips and control solutions (level 1, level 2 and level 3), a lancing device and sterile lancets. With GluNEO™ Professional Blood Glucose Monitoring System, only auto-disabling or single use lancing device must be used.

This blood glucose test system is an in vitro diagnostic device designed for measuring the concentration of glucose in whole blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

6. Indications for use:

▪ GluNEO™ Blood Glucose Monitoring System

The GluNEO™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The GluNEO™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The GluNEO™ Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The GluNEO™ Test Strips are for use with the GluNEO™ Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.

The GluNEO™ Control Solutions are for use with the GluNEO™ Meter and GluNEO™ Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

The GlucoDiary is a PC-based software intended for use in home to help people with diabetes in the review, analysis and evaluation of glucose test results for effective diabetes management. It is intended for use as an accessory to GluNEO™ Blood Glucose Monitoring System.

▪ GluNEO™ Professional Blood Glucose Monitoring System

The GluNEO™ Professional Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh and in venous whole blood. The

GluNEO™ Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The GluNEO™ Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GluNEO™ Professional Test Strips are for use with the GluNEO™ Professional Meter to quantitatively measure glucose (sugar) in venous whole blood samples and fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The GluNEO™ Professional Control Solutions are for use with the GluNEO™ Professional Meter and GluNEO™ Professional Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

The GlucoDiary is a PC-based software intended for use in professional settings to help healthcare professionals in the review, analysis and evaluation of their patients' glucose test results for effective diabetes management. It is intended for use as an accessory to GluNEO™ Professional Blood Glucose Monitoring System.

7. Technological Characteristics:

The GluNEO™ / GluNEO™ Professional Blood Glucose Monitoring System has the same fundamental scientific technology as Ascensia® CONTOUR® Blood Glucose Monitoring System (K062508), and has similar performance specifications and features.

8. Performance Data:

The performance tests for the GluNEO™ / GluNEO™ Professional Blood Glucose Monitoring System were performed in accordance with ISO 15197:2003. Clinical evaluation included method comparison, matrix comparison, user performance and alternative-site blood glucose measurement. Non-clinical performance evaluations were conducted to establish the performance, functionality and reliability characteristics of the GluNEO™ / GluNEO™ Professional Blood Glucose Monitoring System. The device passed all of the tests based on pre-determined Pass/Fail criteria.

Disinfectant CaviWipes with the EPA registration number of 46781-8 has been validated demonstrating complete inactivation of live virus of use with the meter and the reusable lancing device. There was also no change in performance or in the external materials of the meter and the lancing device after 10,980 cleaning/disinfection cycles designed to simulate 3 years of device use.

9. Conclusions:

Infopia Co., Ltd. concludes that the GluNEO™ / GluNEO™ Professional Blood Glucose Monitoring System is safe and effective also, substantially equivalent to the predicate device, Ascensia® CONTOUR® Blood Glucose Monitoring System (K062058) by Bayer HealthCare, LLC.

Ascensia® CONTOUR® Blood Glucose Monitoring System (K062058) by Bayer
HealthCare, LLC.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2013

Infopia Co., Ltd.
C/O Priscilla Chung
LK Consulting Group USA, Inc.
951 Starbuck St. Unit J
FULLERTON CA 92833

Re: K130181

Trade/Device Name: GluNEO™ Blood Glucose Monitoring System
GluNEO™ Professional Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JQP, JJX
Dated: June 24, 2013
Received: July 2, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K 130181

Device Name: GluNEO™ Blood Glucose Monitoring System

Indication for use:

The GluNEO™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh. The GluNEO™ Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared.

The GluNEO™ Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The GluNEO™ Test Strips are for use with the GluNEO™ Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood. Fresh capillary whole blood samples may be drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh.

The GluNEO™ Control Solutions are for use with the GluNEO™ Meter and GluNEO™ Test Strips to check that the meter and test strips are working together properly and the test is performing correctly.

The GlucoDiary is a PC-based software intended for use in home to help people with diabetes in the review, analysis and evaluation of glucose test results for effective diabetes management. It is intended for use as an accessory to GluNEO™ Blood Glucose Monitoring System.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21CFR801 Subpart D) (Part 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k130181

Infopia Co., Ltd.

Indications for Use

510(k) Number K 130181

Device Name: GluNEO™ Professional Blood Glucose Monitoring System

Indication for use:

The GluNEO™ Professional Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in capillary whole blood from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and thigh and in venous whole blood. The GluNEO™ Professional Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The GluNEO™ Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GluNEO™ Professional Test Strips are for use with the GluNEO™ Professional Meter to quantitatively measure glucose (sugar) in venous whole blood samples and fresh capillary whole blood samples drawn from the fingertips, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh.

The GluNEO™ Professional Control Solutions are for use with the GluNEO™ Professional Meter and GluNEO™ Professional Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

The GlucoDiary is a PC-based software intended for use in professional settings to help healthcare professionals in the review, analysis and evaluation of their patients' glucose test results for effective diabetes management. It is intended for use as an accessory to GluNEO™ Professional Blood Glucose Monitoring System.

Prescription Use ☒ AND/OR Over-The-Counter Use ☒
(Part 21CFR801 Subpart D) (Part 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro and Radiological Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro and Radiological Health
Evaluation and Safety

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